UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

HAL UNSCHULD, individually and on behalf of all others similarly situated, Plaintiff, v. DISCOVERY LABORATORIES, INC. and ROBERT J. CAPETOLA Defendants.	:	Civil Action No.: **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff, individually and on behalf of all others similarly situated, by its undersigned attorneys, for its complaint against defendants, based upon, inter alia, the investigation conducted by and through his attorneys, which included, among other things, a review of the defendants' public documents and announcements, Securities and Exchange Commission ("SEC") filings, news articles, wires and press releases regarding defendant Discovery Laboratories, Inc. ("DSCO" or the "Company"), information available on the Internet, including information on the U.S. Food & Drug Administration ("FDA") web site, alleges as follows:

NATURE OF THE ACTION

1. This is a class action on behalf of all persons and entities who purchased DSCO common stock during the period from December 28, 2005 through and including April 25, 2006 (the "Class Period") to recover damages caused by defendants' violations of the federal securities laws by disseminating to the investing public false and misleading statements and

press releases regarding the progress of U.S. regulatory approval for its self-described "lead product," Surfaxin.

2. Throughout the Class Period, defendants repeatedly represented that they anticipated the FDA's approval of Surfaxin in April 2006.

3. On April 25, 2006, the Company revealed that Surfaxin's "stability" (its ability to be stored for long periods without any change in its efficacy or its chemical profile) had not been achieved and that such failure would cause a "significant delay in the U.S. regulatory process." The Company admitted that although it had been testing the "product validation batches" periodically for "stability," stability had never been achieved.

JURISDICTION AND VENUE

4. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a) and the rules and regulations promulgated thereunder by the SEC, including Rule 10b-5, 17 C.F.R. § 240.10b-5.

5. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78aa and 28 U.S.C. § 1331.

6. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). Many of the acts and transactions constituting the violations of the law alleged herein, including the preparation and dissemination to the investing public of false and misleading information, occurred in substantial part in this Judicial District. In addition, DSCO maintains its principal place of business within this Judicial District.

7. In connection with the acts, transactions and conduct alleged herein, defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including

the United States mail, interstate telephone communications and facilities of the national securities exchanges.

THE PARTIES

8. Plaintiff purchased DSCO securities in the amounts and at the prices and times set forth in the annexed certificate, and was damaged as a result thereof.

9. Defendant Discovery Laboratories, Inc. is a corporation organized and existing under the laws of the state of Delaware. The Company's principal executive offices are located in Warrington, Pennsylvania. DSCO describes itself as a biotechnology company developing its proprietary surfactant technology for respiratory diseases.

10. (a) Defendant Robert J. Capetola served, at all times material to the claims set forth herein, as DSCO's President and Chief Executive Officer.

(b) Because of the Capetola's positions with the Company, he had access to the adverse undisclosed information about its business, operations, operational trends, finances, markets and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and report of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof and access to internal corporate documents (including the Company's operating plans, budgets and forecasts and report of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof and via reports and other information provided to them in connection therewith.

11. Capetola was directly involved in the day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company and its business, operations growth, finances, and financial condition, as alleged herein. Capetola was involved in the drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware (ore recklessly disregarded) that the false and misleading statements were being issued regarding the Company and approved or ratified these statements, in violation of the federal securities laws.

12. Capetola was a controlling person of DSCO whose securities were, and are, registered with the SEC pursuant to the Exchange Act, traded on the Nasdaq, and governed by the provisions of the federal securities laws and as such he had a duty to disseminate promptly accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, business, markets, management, and earnings, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly traded securities would be based upon truthful and accurate information. Capetola's and DSCO's misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

13. Capetola had access to the adverse undisclosed information about the ongoing results of the stability testing being conducted by DSCO on Surfaxin as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about DSCO and its business issued or adopted by the Company materially false and misleading.

14. Capetola, because of his position of control and authority as CEO was able to and did control the content of the various SEC filings, press releases and other public statements pertaining to the Company during the Class Period.

15. Defendants are liable participants in a fraudulent scheme and course of business that operated as a fraud or deceit on all purchasers of DSCO common stock from December 28, 2005 to April 25, 2006, by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived plaintiff and the investing public regarding the intrinsic value of DSCO's sock; and (ii) caused plaintiff and other members of the Class to purchase DSCO's stock at artificially inflated prices.

CLASS ACTION ALLEGATIONS

16. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3) on behalf of a class (the "Class") of all persons who purchased DSCO common stock between December 28, 2005 and April 25, 2006, inclusive, and who were damaged thereby. Excluded from the Class are the defendants herein, members of the immediate family of each of the individual Defendants, any parent, subsidiary, affiliate, officer, director or employee of defendant SDSCO, any entity in which any excluded person has a controlling interest, and the legal representatives, heirs, successors and assigns of any excluded person.

17. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at the present time and can only be ascertained from books and records maintained by DSCO and/or its agent(s), plaintiff believes that there are hundreds of members of the Class located

18. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Plaintiff has retained competent counsel experienced in class and securities litigation and intends to prosecute this action vigorously. Plaintiff is a member of the Class and does not have interests antagonistic to, or in conflict with, the other members of the Class.

19. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class purchased DSCO stock at artificially inflated prices and have sustained damages arising out of the same wrongful course of conduct.

20. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(1) Whether the federal securities laws were violated by defendants' acts and omissions as alleged herein;

(2) Whether defendants participated in and pursued the common course of conduct and fraudulent scheme complained of herein;

(3) Whether the documents, reports, filings, releases and statements disseminated to the investing public, including investors in DSCO stock, during the Class Period omitted and/or misrepresented material facts about the future business prospects of DSCO;

(4) Whether defendants acted knowingly or recklessly in omitting to state and/or misrepresenting material facts;

(5) Whether the market prices of DSCO stock during the Class Period was artificially inflated due to the non-disclosures and/or misrepresentations complained of herein; and

(6) Whether plaintiff and the other members of the Class have sustained damages and, if so, the appropriate measure thereof.

21. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since, among other things, joinder of all members of the Class is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it virtually impossible for Class members individually to seek redress for the wrongful conduct alleged. Plaintiff does not foresee any difficulty in the management of this litigation that would preclude its maintenance as a class action.

22. Notice can be provided by a combination of published notice and first class mail using techniques and forms of notice similar to those customarily used in class actions arising under the federal securities laws.

NO STATUTORY SAFE HARBOR

23. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false or misleading statements pleaded in this complaint because the statements pleaded herein were either not identified as "forward-looking statements" when made, or did not refer to meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the statements accompany those statements or both. In addition, defendants are liable for these false forward-looking statements that were identified as

such, because at the time each of those statements were made the speaker actually knew the forward-looking statement was false and/or misleading and the statement was authorized and/or approved by an executive officer of the Company, who actually knew those statements were false and misleading.

24. DSCO describes itself as a biotechnology company developing its proprietary surfactant technology as "surfactant" Replacement Therapies ("SRT") for respiratory diseases. The company's press releases state:

> Discovery's SRT pipeline is focused on significant respiratory conditions prevalent in the neonatal intensive care unit, critical care and other hospital settings. Discovery's lead product, Surfaxin®, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA.

25. On December 28, 2005, defendants entered into an agreement to acquire the manufacturing operations of Laureate Pharma, Inc. (a wholly-owned subsidiary of Safeguard Scientifics, Inc.) in Totowa, New Jersey, for $16 million. Robert J. Capetola, Ph.D., President and Chief Executive Officer of DSCO, commented:

> We are preparing our organization for the anticipated approval of Surfaxin in April 2006 and its commercial launch in the second quarter. We believe our Surfactant Replacement Therapy pipeline, with Surfaxin as the cornerstone, holds the promise to revolutionize the treatment of respiratory diseases and it is strategically important to control key operations of a pharmaceutical business – from the conduct of clinical trails to the quality of manufacturing to commercializing our products. We have an established development, clinical and regulatory infrastructure and we expect to complete the build of our United States commercial sales organization by the second quarter of 2006. With this manufacturing acquisition, we believe we will have secured the key strategic operations for Discovery to become a fully-integrated biotechnology company.

26. On January 26, 2006, defendants represented:

> Surfaxin has already received an Approvable Letter from the FDA for the prevention of RDS in premature infants and anticipates potential approval in April 2006.

27. On February 23, 2006, defendants announced financial results for the fourth quarter and year ended December 31, 2005. Robert J. Capetola, Ph.D., President and Chief Executive Officer of DSCO commented:

> This past quarter, we believe we have significantly strengthened our Company, both financially and operationally in preparation for the potential FDA approval in April 2006 and U.S. commercial launch in the second quarter of 2006 of our lead product, Surfaxin. We have raised $29.0 million in capital, secured our own manufacturing operation – a key strategic asset for Surfaxin and our pipeline, and are now in the final stage of building our specialty neonatal U.S. commercial capability. Important to the development of our surfactant replacement therapy (SRT) pipeline, we established a strategic alliance with Chrysalis Technology (a division of Philip Morris USA) where we acquired rights to a novel aerosol generating technology being developed to enable the delivery of SRT to the deep lunch. The successful application of our SRT and Chrysalis' aerosol technology holds the promise, for the first time, of producing surfactant-based therapies that may revolutionize the treatment of serious respiratory conditions such as neonatal respiratory failure, acute lung injury, chronic obstructive pulmonary disorder, asthma, cystic fibrosis and others.

28. On March 16, 2006, Discovery filed its Form 10-K for the year-ended December 31, 2005 with the SEC. In the 10-K, signed by Defendant Capetola, defendants disclosed:

> In February 2005, we received an Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. As part of the review of the Surfaxin NDA, the FDA, in January 2005, issued a Form 483 to our then contract manufacturer, Laureate Pharma, Inc. citing inspectional observations related to basic quality controls, process assurances and documentation requirements that support the commercial production process necessary to comply with current good manufacturing practices (cGMPs). To address the inspectional observations, we and Laureate implemented improved quality systems and documentation controls believed to support the FDA's regulatory

> requirements for the approval of Surfaxin. In December 2005, we purchased the manufacturing operations of Laureate in Totowa, NJ.
>
> Our previously submitted responses to the Approvable Letter were accepted by the FDA as a complete response as of October 5, 2005. Assuming that the corrective actions made to the Surfaxin manufacturing operation in Totowa, NJ are adequate, we anticipate that our NDA will be approved in April 2006 and that the U.S. commercial launch of Surfaxin will occur late in the second quarter of 2006.
>
> In January 2006, the FDA granted us Fast-Track designation for Surfaxin for the treatment and prevention of BPD in premature infants. Designation as a Fast-Track product means that the FDA has determined that the drug is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such a condition, and that the FDA will facilitate and expedite the development and review of the application for the approval of the product. The FDA generally will review an NDA for a drug granted Fast-Track designation within six months instead of the typical one to three years.

29. On April 5, 2006, defendants represented:

> Discovery Laboratories, Inc. today announced that it has received a second Approvable Letter from the U.S. Food and Drug Administration (FDA) for Discovery's lead product candidate, Surfaxin (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants.
>
> The Approvable Letter is an official notification from the FDA and contains conditions that must be satisfied by Discovery prior to obtaining final U.S. marketing approval. Specifically, the FDA is requesting certain information primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the NDA. The information predominately involves the further tightening of active ingredient and drug product specifications and related controls. Consistent with previous review, the FDA does not have any clinical or statistical comments.

30. On April 19, 2006, DSCO announced that it has entered into a new Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Ltd. ("Kingsbridge"), in which Kingsbridge has committed to provide up to $50 million of capital to support DSCO's future

growth. John G. Cooper, Executive Vice President and Chief Financial Officer of Discovery Labs, commented:

> This new CEFF, coupled with our existing cash, should provide us with financial resources adequate to progress Surfaxin® through the final stages of the U.S. and European regulatory review and approval processes for our initial indication, Respiratory Distress Syndrome in premature infants. In addition, it will allow us to support our manufacturing and commercialization initiatives and our key SRT pipeline programs, Surfaxin for Bronchopulmonary Dysplasia and Aerosurf™.

31. Finally, on April 25, 2006, defendants revealed that:

> U.S. regulatory approval of the company's pediatric drug Surfaxin is again being delayed over manufacturing problems.
>
> Shares of the Warrington, Pa. - based company sank 53% to close at $2.20.
>
> Discovery announced that test batches of Surfaxin, prepared at the request of the FDA, indicated problems with the product's stability. As a result, Discovery will have to prepare additional test batches, which will likely result in a "significant" delay in the product's approval.
>
> Discovery added that it was also shelving plans to build a commercial infrastructure for the product.

SCIENTER ALLEGATIONS

32. As alleged herein, defendants acted with scienter in that they knew or recklessly disregarded that the public documents and statements issued or disseminated by them were materially false and misleading and/or omitted to state material facts necessary to make their statements not misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or

dissemination of such statements or documents as primary violations of the federal securities laws.

33. Defendants were aware that the FDA conducted a pre-approval inspection of the manufacturing facility in January 2005 which resulted in the issuance of a Form FDA-483. The company responded by implementing an extensive cGMP corrective action plan. Subsequently, the FDA spent three weeks inspecting the facility in March and April 2006, concluding on April 7, 2006 after receipt of the second Approval Letter. Defendants were clearly aware of the FDA inspections, their continue concern with the manufacturing processes and facilities and the resulting delay in approval which would occur.

LOSS CAUSATION/ECONOMIC LOSS

34. During the Class Period, as detailed herein, defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated DSCO's stock price and operated as a fraud or deceit on Class Period purchasers of DSCO stock by misrepresenting the Company's manufacturing facilities and processes issues. Later, however, when defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market, DSCO stock fell precipitously as the prior artificial inflation came out of DSCO's stock price. As a result of their purchases of DSCO stock during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

COUNT I

Violation of Section 10(b) of the Exchange Act and Rule 10b-5 of the Securities and Exchange Commission

35. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

36. This Count is asserted against defendants and is based upon section 10(b) of the 1934 Act. 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder.

37. During the Class Period, defendants directly engaged in a common plan, scheme, and unlawful course of conduct, pursuant to which it knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon plaintiff and the other members of the Class, and made various deceptive and untrue statements of material facts and omitted to state material in order to make the statements made, in light of the circumstances under which they were made, not misleading to plaintiff and the other members of the Class. The purpose and effect of said scheme, plan, and unlawful course of conduct was, among other things, to induce plaintiff and the other members of the Class to purchase DSCO stock during the Class Period at artificially inflated prices.

38. During the Class Period, defendants, pursuant to said scheme, plan, and unlawful course of conduct, knowingly and recklessly issued, caused to be issued, participated in the issuance of, the preparation and issuance of deceptive and materially false and misleading statements to the investing public as particularized above.

39. As a result of the dissemination of the false and misleading statements set forth above, the market prices of DSCO stock was artificially inflated during the Class Period. In ignorance of the false and misleading nature of the statements described above and the deceptive

and manipulative devices and contrivances employed by said defendants, plaintiff and the other members of the Class relied, to their detriment, on the integrity of the market prices of the stock in purchasing DSCO stock. Had plaintiff and the other members of the Class known the truth, they would not have purchased said stock or would not have purchased them at the inflated prices that were paid.

40. Plaintiff and the other members of the Class have suffered substantial damages as a result of the wrongs herein alleged in an amount to be proved at trial.

41. By reason of the foregoing, defendants directly violated section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon plaintiff and the other members of the Class in connection with their purchases of DSCO stock during the Class Period.

COUNT II

For Violation Of Section 20(a) Of The Exchange Act (Against Capetola)

42. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

43. Capetola, was the controlling person of the Company within the meaning of section 20(a) of the Exchange Act as alleged herein. By virtue of his high-level positions, participation in and/or awareness of the Company's operations, and/or intimate knowledge of the Company's plans and implementation thereof, he had the power to

influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements that plaintiff contends are false and misleading. Capetola was provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

44. In particular, he had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

45. By virtue of his position as controlling person, he is liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of the wrongful conduct, plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's stock during the Class Period.

WHEREFORE, plaintiff, on his own behalf and on behalf of the Class, pray for judgment as follows:

Declaring this action to be a proper class action and certifying plaintiff as class representative under Rule 23 of the Federal Rules of Civil Procedure;

A. Awarding compensatory damages in favor of plaintiff and the other members of the Class against the Defendants for the damages sustained as a result of the wrongdoings of the Defendants, together with interest thereon;

B. Awarding plaintiff the fees and expenses incurred in this action,

including reasonable allowance of fees for plaintiffs attorneys, and experts;

C. Granting such other and further relief as the Court may deem just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY

Dated: April 28, 2006

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